

Recommendation on Component Analysis

SACHRP recommends that FDA and OHRP issue joint guidance, or if that is not feasible, consistent guidance, explaining how to perform component analysis in the application of Subpart D. Such guidance should include:

1. How to apply 50.51 (404), 50.53 (406), and 50.52 (405) to controlled trials and specifically to placebo-controlled trials,
2. How component analysis does or does not apply to social and behavioral research,
3. How component analysis might impact parental permission and child assent and
4. What documentation from the IRB must be or should be included.

Furthermore, SACHRP recommends that education and training materials for IRB members and investigators be made available and a communication plan developed.